

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
WICHITA FALLS DIVISION

DORIS RAUB

V.

MATRIX INITIATIVES, INC., a Delaware Corporation, f/k/a Gumtech International, Inc. and ZICAM, L.L.C. f/k/a Gel Tech, LLC an Arizona Limited Liability Corporation

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Civil Action No. 7:11-CV-032

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT (FRCP 56)

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MOTION FOR SUMMARY JUDGMENT

A. Introduction and Grounds for Summary Judgment

The common cold is the most common cause of smell disorders in the general population, and smell disorders are a common affliction in the adult population, particularly in individuals over the age of 60. Recent epidemiological research demonstrates that close to 20% of all adults have persistent or permanent smell dysfunction, and the prevalence and incidence of smell disorders climbs with age – 50% of adults over the age of 60 have dysfunction, and those over the age of 70 whose smell function remains intact have a 19.3% chance of developing a smell disorder within a five year period.¹ A secondary consequence of smell loss is the impairment of taste function, or, more precisely, the ability to fully appreciate flavor in foods and beverages.

Plaintiff Doris Raub (“Raub”) was 76 years old in February 2009 when she developed one of the worst colds she had ever experienced, which progressed to bronchitis.² She used an over-the-counter oral cold remedy, Zicam Cold Remedy Oral Mist (“ZCROM”) for three or four days, but the cold persisted.³ Several weeks later, after she got over the cold, she noticed that her sense of taste and smell function had deteriorated substantially, and by her self-report (though not substantiated with any formal diagnostic test) her sense of smell was completely gone, a condition known as “anosmia.”⁴ No treating physician has ever attributed Raub’s smell and taste loss to ZCROM,⁵ but based on her daughter’s advice that a *different* Zicam cold remedy product

¹ See Report of Kevin Kip (“Kip Report”) ¶¶ 39, 41-46 (App. pp. 13-18); Report of Marion Joseph Fedoruk (“Fedoruk Report”) § 5.1, p. 6., § 6, p. 17 (App. pp. 59, 70).

² Deposition of Doris Raub (“Raub Dep.”) pp. 7:3-4, 35:22-36:3, 38:13-24, 58:21-60:10, 62:13-21, 63:4-16 (App. 193, 198-200, 204-208); Fedoruk Report § 4, p. 5, § 6, p. 17 (App. pp. 58, 70); Deposition of Sharon Rose Yap Palomo, M.D. (“Palomo Dep.”) pp. 14:16-20, 15:19-16:2 (App. pp. 159-161).

³ Raub Dep. p. 64:11-12. (App. p. 209); Fedoruk Report § 4, p. 5 (App. p. 58).

⁴ Raub Dep. pp. 74:17-75:19, 74:21-23, 80:6-11. (App. pp. 214-215, 217); Fedoruk Report § 4, p. 5, § 6, p. 16 (App. pp. 58, 69); Deposition of Cameron Godfrey, M.D. (“Godfrey Dep.”) pp. 29:13-31:16, 33:9-12 (App. pp. 179-182).

⁵ Raub Dep. pp. 82:3-7, 85:6-15, 87:11-17. (App. pp. 219, 221-222); Palomo Dep. p. 36:5-8 (App. p. 169); Godfrey Dep. pp. 34:25-35:2 (App. pp. 183-184).

– one administered *intranasally* – had been in the news as a potential cause of smell loss, Plaintiff ascribed her condition to this oral cold remedy and filed this suit.⁶

In this diversity product liability/personal injury case, Raub asserts claims for negligence, gross negligence, fraud, malice, breach of warranty, Texas Deceptive Trade Practice Act (“DTPA”) violations and strict liability for the design, manufacture and marketing of Zicam®, as well as for misrepresentations as to the safety of ZCROM.⁷

Defendants are entitled to summary judgment on all claims. First, Raub has no reliable scientific evidence that her use of ZCROM in February 2009 could have caused, or did cause, her to lose her sense of smell and taste. Causation is a necessary element in all of Raub’s claims for recovery. In addition:

Design Defect Claims: To recover, Plaintiff must prove that (1) the product was defectively designed so as to render it unreasonably dangerous, (2) a safer alternative design existed, and (3) the defect caused the claimed injury. Plaintiff has no evidence to satisfy these elements, and the third element also fails because her expert testimony on causation is inadmissible.

Manufacturing Defect Claims: To recover, Plaintiff must prove that the product she used deviated from specifications and was unreasonably dangerous, and this defect caused her injury. Plaintiff has no evidence at all of these elements, and causation also fails because her expert testimony on causation is inadmissible.

Marketing Defect Claims: To recover for a failure to warn, Plaintiff must prove that (1) a risk of harm which may arise from the intended or reasonably anticipated use of the product; (2) the defendant knew or reasonably should have foreseen the risk of harm at the time the

⁶ Raub Dep. p. 17:6-25, 19:23-20:1, 89:2-10. (App. pp. 194, 196-197, 223).

⁷ See Plaintiff’s Complaint (App. pp. 134-143).

product was sold; (3) the product contained no warning of this risk; (4) the absence of warning renders the product unreasonably dangerous to the user of the product; and (5) the failure to warn caused the user's injury. Plaintiff has no evidence to satisfy the first four elements and medical causation, and causation also fails because her expert's causation testimony is inadmissible.

Breach of Warranty Claims: Though Plaintiff asserts a breach of express warranty claim, she identifies no express warranty and appears to rely solely on a warranty of fitness for ordinary purposes arising from the sale of the product. To recover, Plaintiff must prove that (1) the product was defective because it was unfit for its purpose, (2) the defect existed when the product was sold, and (3) the defect caused the injury. For the same reasons the defect claims fail, so does the claim for breach of warranty.

Negligence: To prevail on her negligence claims, Plaintiff must prove that her injury was caused by a defect in the product and the defect resulted from a failure to exercise ordinary care in the design, manufacture or marketing of the product. Plaintiffs' claims for negligence fail for the same reasons as her defect claims, and for the additional reason that she has no evidence that defendants violated any standard of care.

DTPA claim: Despite her allegations, Raub has failed to state a claim under the DTPA because her claim is for bodily injury, and such claims are simply not permitted by the DTPA. There are limited exceptions, but Raub does not qualify for any of them.

Gross Negligence and Malice: To recover, Raub must establish that Defendants committed an act or omission which objectively and subjectively involved an extreme degree of risk, and despite that risk, Defendants proceeded with conscious indifference to safety. There is no evidence of any of these elements.

Fraud and Misrepresentation: Raub alleges that Defendants misrepresented that ZCROM was safe, and failed to disclose that the product could cause smell and taste loss. This is nothing more than a failure to warn/defective marketing claim, and fails for the same reasons. In any event, Plaintiff has failed to establish any misrepresentation concerning the safety of ZCROM, much less identified a specific statement that she relied on and which caused her injury.

Punitive Damages: Raub has produced no evidence of gross negligence, malice, or fraud and therefore cannot recover punitive damages.

B. Factual Background

1. Raub's Viral Infection, Use Of ZCROM, And Medical Treatment

Raub used ZCROM for 3-4 days in February 2009 to combat the worst cold she had ever experienced. At the time of use she was suffering from a stopped up nose, cough, fever, sneezing, and head and chest congestion. Both the duration and the severity of her symptoms were worse than usual; though her colds usually last 4-5 days, she "just didn't seem to get over it."⁸

Upon using ZCROM, Raub experienced no adverse sensations or side effects; she ceased using it because it did not seem to be helping her cold symptoms.⁹

A few days after she stopped use, with her cold still persisting, Raub went to see her treating physician, Dr. Sharon Rose Yap Palomo on February 27, 2009. Raub presented with a history of fever, cough, head and chest congestion, and yellow sputum for two weeks. At that time, Raub had not experienced any smell or taste loss, and did not report any such loss. On physical examination Dr. Palomo documented post-nasal drip, congestion, sore throat, fever,

⁸ Raub Dep. pp. 39:2-4, 58:21-60:24, 63:12-16, 64:11-12, 81:2-6 (App. pp. 201, 204-206, 208-209, 218); Fedoruk Report § 4, p. 5 (App. p. 58).

⁹ Raub Dep. pp. 71:15-72:7, 73:1-2 (App. pp. 211, 213).

fatigue, and course breath sounds. Dr. Palomo diagnosed Raub with an upper respiratory infection which had developed into bronchitis, and prescribed the antibiotic Avelox for the infection, Nasonex nasal spray for the head and chest congestion, and Tesselon for the cough.¹⁰

Raub first noticed her smell deficit in April 2009, and she first noticed an alteration in her ability to taste shortly before that, in late March 2009. She first reported the problem to a physician on April 2, 2009, when she saw Dr. Palomo.¹¹

By this time, Raub had become convinced that her smell and taste loss was due to ZCROM. When she had told her daughter, Nannette, of her smell and taste problem, her daughter said she had read online about lawsuits against the makers of “Zicam” and allegations that use of “Zicam” could cause smell and taste impairment. Based on this conversation, Raub concluded that her problem with her taste and smell was due to her use of ZCROM.¹²

Raub presented to ENT Dr. Cameron Godfrey on July 28, 2009. Though there are generally accepted objective diagnostic tests to quantitatively and qualitatively evaluate smell function, Dr. Godfrey administered an improvised subjective “test” to Raub, basically waving odorous substances under her nose and asking her if she could identify them. There has never been any objective verification of Raub’s smell and taste dysfunction, or its degree. Raub claims her loss of smell and taste is complete.¹³ Dr. Godfrey diagnosed anosmia based on Raub’s report

¹⁰ Raub Dep. pp. 62:9-64:12, 68:7-10 (App. pp. 207-210); Palomo Dep. pp. 12:7-13:23, 14:16-20, 15:11-16:8 (App. pp. 157-161); Fedoruk Report § 4, p. 5 (App. p. 58).

¹¹ Raub Dep. pp. 74:17-75:19, 80:6-11, 81:10-17 (App. pp. 214-215, 217-218). Dr. Palomo has no record or recall of this report of smell and taste loss. Palomo Dep. pp. 16:15-19, 17:23-18:7, 19:4-24, 25:6-15, 27:3-14, 35:12-15 (App. pp. 161-166, 168).

¹² Raub Dep. pp. 17:6-18:17, 19:23-20:1, 82:8-15 (App. pp. 194-197, 219).

¹³ Raub Dep. pp. 74:21-23, 83:9-25 (App. pp. 214, 220); Godfrey Dep. pp. 20:10-12, 29:13-31:16, 33:9-12 (App. pp. 176, 179-182); Fedoruk Report § 6, p. 16 (App. p. 69).

that she was unable to smell.¹⁴ Based on taste testing, Dr. Godfrey did not diagnose Raub with any loss of taste.¹⁵

Raub claims she told Dr. Godfrey that she had used “Zicam” and suspected it was the cause.¹⁶ Dr. Godfrey was unable to isolate a cause, and said it could be a medication she took,¹⁷ or it could be a virus.¹⁸ No health care provider has ever told Raub that her loss of smell or taste was caused by ZCROM.¹⁹

2. The Product

ZCROM is a homeopathic over the counter cold remedy product. It is a liquid solution dispensed from a spray bottle which produces a fine mist, intended to be sprayed into the mouth three to four times, then be retained for 15 seconds and swallowed. It is to be used every three hours. The active ingredients are zinc gluconate and zinc acetate.²⁰

ZCROM is very different in all these respects than another Zicam Cold Remedy product that was marketed at the time of Raub’s use, Zicam Cold Remedy Nasal Gel. That product is not a liquid solution; it is a viscous gel. Its active ingredient is zinc gluconate alone, and most importantly, it is delivered via either a nasal spray or an intranasal swab, into the lower nasal cavity, not the mouth.

¹⁴ Godfrey Dep. p. 33:9-12 (App. p. 182).

¹⁵ *Id.* p. 31:17-21 (App. p. 181).

¹⁶ Raub Dep. p. 83:20-25. (App. p. 220); Godfrey Dep. pp. 20:21-21:4 (App. pp. 176-177).

¹⁷ Raub Dep. p. 85:6-15 (App. p. 221). The prescribing information for the antibiotic Avelox, which Raub took for her respiratory infections *after* she stopped using ZCROM and *before* she experienced smell and taste loss advises that reported adverse reactions include dysgeusia (impaired taste function) and dry mouth, another condition Raub has complained of (and which she relates to her ZCROM use). Avelox prescribing information Table 3 (App. pp. 271-273); Raub Dep. pp. 50:23-51:11, 79:20-25 (App. pp. 202-203, 216). The prescribing information for Nasonex Nasal Spray advises that adverse reactions reported include disturbances of taste and smell. Nasonex prescribing information § 6.2 (App. p. 256).

¹⁸ Raub Dep. p. 85:6-15. (App. p. 221); Godfrey Dep. pp. 16:11-17:16, 28:20-29:3, 36:9-24, 37:19-21, 40:17-42:10 (App. pp. 172-173, 178-179, 185-186, 188-190).

¹⁹ Raub Dep. p. 87:11-14. (App. p. 222); Palomo Dep. pp. 30:19-25, 36:5-8 (App. pp. 167, 169); Godfrey Dep. pp. 34:25-35:2 (App. pp. 183-184).

²⁰ Fedoruk Report § 5.2, pp. 6-7, § 6, p. 8 (App. pp. 59-61); Report of Christine Wood (“Wood Report”) p. 4 (App. p. 113); ZCROM packaging (App. pp. 298-299); ZCROM labeling (App. pp. 326-327).

3. Smell and Taste

The injury alleged by Raub is loss of smell and taste. The sense of smell, or olfaction, occurs when tiny volatile odorant molecules enter the nasal cavity and are drawn up to the olfactory nerves, also called “the olfactory neuroepithelium,” or more colloquially, “the smell tissue.” There, receptors in a mucus layer covering the smell tissue receive the odorants and pass them through the smell tissue and into the olfactory bulb and the brain, where they are processed, resulting in the sensation of specific odors.²¹

The sense of taste, per se, takes place on the tongue, and is unaffected by smell deficits. But in fact, the appreciation of *flavor* is primarily provided by odors produced by the food we eat. Consequently, people who have an impaired sense of smell often complain of a loss of “taste,” but they are actually describing a loss of flavor secondary to smell deficit. Thus, in this case, Raub’s loss of taste is simply a sequelae of the smell loss. On testing, Dr. Godfrey found Raub’s sense of taste intact.²²

Plaintiff’s theory of the case is that the zinc component of the active ingredients in ZCROM is able to pass from the mouth up into the nasal cavity through the nasopharynx, then climb up to the very top and rear of the nasal cavity where the smell tissue is located, where the interaction between the zinc and the smell tissue causes the tissue to be permanently damaged, thus eliminating smell function.²³ There is no reliable scientific evidence that ZCROM reaches the smell tissue and causes smell loss. Plaintiff’s causation theory is based on an unsupported extrapolation from disputed evidence concerning a different product in a different formulation with a different manner and route of administration, as well as a number of other deviations from

²¹ Fedoruk Report § 5.1, p. 6 (App. p. 59).

²² Godfrey Dep. p. 31:17-21 (App. p. 181).

²³ Fedoruk Report § 6, p. 9 (App. p. 62).

sound scientific methodology and reasoning. Indeed, while intranasal application of a zinc gluconate gel has been alleged to cause smell and taste loss, oral ingestion of zinc gluconate is often used as a *therapy to improve* smell function.²⁴

4. Zicam Intranasal Cold Remedy Gel Litigation

Defendants Matrixx Initiatives, Inc. and Zicam LLC market a line of cough and cold products under the brand name Zicam. From 1999 to 2009 the company sold a product known as “Zicam Cold Remedy Nasal Gel,” containing zinc gluconate in a viscous gel administered intranasally with a spray bottle, and later also via nasal swab. In late 2003 the company introduced several oral cold remedy products, including lozenges, RapidMelt chews, and ZCROM. The company has also marketed a variety of non-zinc products, for allergy relief, sinus decongestion, nasal moisturizing, cough suppression, and the like.²⁵

In 2003, an ENT in Colorado, Dr. Bruce Jafek, published a “poster” at an American Rhinological Society Meeting in the form of a “case series,” claiming he had seen several patients in his clinic for smell loss who had given a history of using the Zicam Cold Remedy Nasal Gel, experienced a burning sensation in their nasal cavities, and soon thereafter experienced a loss of smell and consequential impairment of taste. Dr. Jafek later published his case series in a medical journal.²⁶ Matrixx convened a multi-disciplinary Scientific Advisory Board (“SAB”) to evaluate Dr. Jafek’s hypothesis that smell loss was caused by the product rather than the cold the patients were treating.²⁷ The SAB’s analysis resulted in an epidemiology

²⁴ See Kip Report ¶ 16 (xii) (App. pp. 4-6).

²⁵ Wood Report p. 4 (App. p. 113).

²⁶ See Kip Report ¶ 48 (App. p. 19).

²⁷ It is undisputed that the most common established causes of persistent or permanent smell impairment are viral infections, including upper respiratory infections like the common cold, and nasal and sinus disease, including rhinitis and sinusitis. Fedoruk Report § 7, p. 21 (App. p. 74); Godfrey Dep. pp. 16:11-17:16, 28:20-29:3, 36:9-24, 37:19-21, 38:3-5 (App. pp. 172-173, 178-179, 185-187). Because Zicam Cold Remedy is used to treat the cold, it is not surprising that a small number of users lose their senses of smell and taste while using the product to treat a cold,

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study to characterize the common causes of smell loss,²⁸ distribution studies to investigate whether the viscous gel could reach the smell tissue,²⁹ and animal toxicology studies to evaluate the dose-response relationship between application of Zicam to smell tissue and damage to the tissue and smell function.³⁰ The epidemiology study confirmed that respiratory infections and nasal and sinus disease were ubiquitously associated with office visits for treatment of smell dysfunction; the distribution study showed that intranasal spray application of the gel did not deliver any of the gel to the smell tissue, even under conditions of egregious misuse; and the animal study suggested that it would take delivery of an extreme overdose of the gel to the smell tissue to cause any appreciable damage, and an even larger overdose to impair smell function, based on the mouse model. The SAB concluded that the theory that the nasal gel causes smell loss was without any sound scientific basis.³¹

Nevertheless, Dr. Jafek publicized his theory on *Good Morning America* in February 2004, attorney solicitation websites sprang up and media attention intensified, and hundreds of lawsuits were filed claiming smell and taste loss from the nasal gel.³² Dr. Jafek was eventually exposed as a junk scientist, excluded from testifying under Rule 702 by a series of decisions. Other experts who sought to testify that Zicam Cold Remedy Nasal Gel had similarly deficient

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especially given the tens of millions of units sold and the hundreds of millions of colds treated. *See* Godfrey Dep. pp. 40-17-42:10 (App. pp. 188-190).

²⁸ B. Nguyen-Khoa et al., Epidemiological study of smell disturbance in two medical insurance claims populations. *Arch Otolaryngol Head Neck Surgery* 2007; 133 (8): pp. 748-757 (App. pp. 228-237).

²⁹ J. Herranz Gonzalez-Botas et al., Anatomical distribution and transport of a liquid nasal gel, *Acta Otorrinolaringologica Espanol* 2006; 57 (3): pp. 130-133 (App. pp. 245-251).

³⁰ B. Slotnick, et al.; Olfaction and olfactory epithelium in mice treated with zinc gluconate, *The Laryngoscope* 2007; 117: pp. 743-749 (App. pp. 238-244).

³¹ Matrixx Initiatives, Inc. Form 8-K Statement, September 29, 2004 (App. pp. 319-321); Wood Report p. 7 (App. p. 116).

³² *See* Kip Report ¶ 54 (App. pp. 23-25); Fedoruk Report § 6, p. 17 (App. p. 70).

scientific foundations, and were likewise excluded.³³ The primary common reason cited by these various judges was the lack of any reliable scientific evidence that intranasal spray application of the gel could deliver any toxic dose to the smell tissue, which is clustered in a sheltered location at the very top and rear of the nasal cavity, a fairly inaccessible location.³⁴

In June 2009, however, the FDA issued a Warning Letter to Matrixx and a press release announcing that the number of anecdotal reports of smell and taste loss after Zicam Cold Remedy Nasal Gel use raised concerns about its safety, and the agency was therefore exercising its discretion to treat the product as a “new drug” rather than an exempt homeopathic remedy.³⁵ Because no New Drug Application had been filed and approved, Matrixx voluntarily withdrew the intranasal gel from the market. The FDA action was highly publicized and breathed new life into the product liability litigation, resulting in increased attorney solicitation, the filing of hundreds of lawsuits, including a number of economic injury class actions, and the eventual creation of an MDL proceeding in late 2009 venued in the District of Arizona, Judge Frederick J. Martone.

The FDA reviewed the complaint history and the scientific evidence relating to the safety of *all* of the Zicam Cold Remedy products, including the oral products such as ZCROM. But it

³³ In all, ten motions to exclude causation experts were decided under FRE 702 between September 2006 and March 2009, and all ten were granted. See *In re Zicam Cold Remedy Marketing, Sales Practices, & Prods. Liab. Litig.*, 2011 WL 798898, *1 (D. Ariz. Feb. 24, 2011) (*In re Zicam*); see also *Polski v. Quigley Corp.*, 538 F.3d 836 (8th Cir. 2008) (affirming exclusion of Dr. Jafek’s causation opinions regarding another intranasal zinc gluconate cold remedy).

³⁴ See, e.g., *Sutherland v. Matrixx Initiatives, Inc.*, 2006 U.S. Dist. LEXIS 96652, *18-25 (N.D. Ala. Nov. 7, 2006); *Hilton v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 73264, *5-7 (N. D. Tex. Feb. 20, 2007); *Wyatt v. Matrixx Initiatives, Inc.*, 2007 U.S. Dist. LEXIS 67986, *9-13 (N.D. Ala. Mar. 30, 2007); see also Godfrey Dep. pp. 18:18-19:13 (App. pp. 174-175) (discussing the location of the smell tissue).

³⁵ See Warning Letter June 16, 2009 (App. pp. 322-325). The FDA was not required to find a causal relationship between the product and smell loss to withdraw the homeopathic exemption, and it did not; rather, the agency only needed to find a “safety signal” to take action. See Kip Report ¶ 80 (App. p. 38). Courts consistently have agreed that agency action is not probative of causation because of the relaxed public policy standards applied by regulatory agencies. See, e.g., *In Re Zicam*, 2011 WL 798898, *11, 18; *McClain v. Metabolife Int’l Inc.*, 401 F.3d 1233, 1249 (11th Cir. 2005).

took no action against the oral products. Though it caused the intranasal gel products to be withdrawn from the market, the homeopathic exemption for the oral products remains intact for the oral products, including ZCROM, and they remain on the market.³⁶

C. Procedural History

This suit was filed during the course of the MDL, on February 3, 2011, in District Court for Wichita County and removed to this Court, then transferred into the MDL.

In the MDL, the sole issues to be adjudicated through Daubert challenges and summary judgment motions were issues common to all plaintiffs, including general causation, *i.e.*, the ability of Zicam Cold Remedy Nasal Gel to cause smell loss and consequential taste loss. The collective Plaintiffs retained and disclosed a new set of experts who relied on a novel set of theories to support their opinions that intranasal application of the Zicam Cold Remedy Nasal Gel resulted in delivery of zinc gluconate to the smell tissue. Some of these theories and opinions were excluded by the MDL Judge under Rule 702, but some of them survived the Daubert challenge. Summary judgment on general causation was denied, the MDL Judge finding a triable issue of material fact as to the general causation issue. All case-specific issues, including specific causation (whether the product used by the Plaintiff was the actual cause of the individual Plaintiff's injury) were remanded to the transferor courts for discovery, motion practice, and, if necessary, trial.³⁷

Prior to remand of this case, Defendants filed a no-evidence motion for summary judgment, because Plaintiffs had produced no general causation evidence that ZCROM, or any of

³⁶ See Wood Report p. 8 (App. p. 117); Kip Report ¶ 80 (App. p. 38); Fedoruk Report § 2, p. 2, § 6 pp. 8-9 (App. pp. 61-62).

³⁷ MDL Order Aug. 9, 2011, Doc. No. 1504 (App. pp. 304-308).

the oral Zicam Cold Remedy products, were shown to cause smell and taste loss.³⁸ The MDL judge denied the motion without prejudice to allow Plaintiff Raub a further opportunity to develop the expert testimony she would need to survive summary judgment.³⁹

Plaintiff has taken no depositions to adduce any evidence concerning the design, manufacture, and marketing of ZCROM. Defendants deposed the Plaintiff and her husband and took the depositions of three treating physicians. Plaintiff disclosed a single expert to testify that ZCROM caused her smell and taste loss, M.D. Stephen Pike. No other experts were designated by Plaintiff to testify on any other issue. Defendants designated the testimony of an epidemiologist, Kevin Kip Ph.D., an M.D. toxicologist, Dr. Joseph Fedoruk, and a labeling expert, Dr. Christine Wood.

Dr. Pike's report is the sole expert evidence Plaintiff relies on to support her claims. Because Defendants are separately moving to exclude Dr. Pike's causation testimony under Rule 702, the methodological and foundational shortcomings of his causation opinions under Rule 702 are reserved for detailed discussion in that motion, which will be filed imminently.⁴⁰ Even though he is Plaintiffs' sole expert witness, Dr. Pike offers opinions on only one subject – *causation*. Summary judgment is required because he offers no opinions on defect, unreasonable danger, alternative designs, or any subject other than causation.⁴¹

³⁸ Defendants' Motion for Summary Judgment May 4, 2011, Doc. No. 1446 (App. pp. 309-318).

³⁹ MDL Order July 6, 2011, Doc. No. 1491 (App. pp. 300-303).

⁴⁰ Under the Case Management Scheduling Order, June 4 is the last day to file a dispositive motion as well as the first day to file a Daubert motion. Defendants will file the Rule 702 motion within the next week. Because, if granted, it provides a further basis for granting this motion – no evidence of causation – and because they are related, the Court may wish to decide the motions together.

⁴¹ Report of Steven Pike, M.D. ("Pike Report") (App. pp. 76-109). As we will discuss in detail in the Motion to Exclude, Dr. Pike improperly extrapolates from unreliable evidence concerning the *intranasal application* of the *viscous Zicam nasal gel* to reach unsupported conclusions about the *oral application* of the *liquid ZCROM*. As explained in the reports of experts Fedoruk and Kip, those are improper extrapolations and Dr. Pike's methodology, analysis and conclusions are unsupported by any reliable scientific evidence. See Kip Report ¶¶ 16 (vi-vii), 53, 72-

(Continued)

Plaintiff's pretrial disclosures identify no other evidence to support any of the other elements of her claims. In her Rule 26(a) Initial Disclosure dated May 4, 2011, Raub identified as witnesses with discoverable information that she "may use to support [her] claims" (FRCP 26(a)(1)(A)(i)) herself, Defendants Matrixx and Zicam LLC, and her medical providers who "may be called upon to testify as to the nature and extent of their participation and provision of health care services or health care treatment of any kind or nature to Plaintiff" Plaintiff reserved the right to supplement the response, and in fact served a Supplemental Disclosure Response June 16, 2011, but no witnesses were added and no substantive changes were made.

Pursuant to FRCP 26(a)(1)(A)(ii), Plaintiff also identified the documents and tangible things she "may use to support [her] claims" The only documents identified were her medical records. Again, Plaintiff reserved the right to supplement the response, but her Supplemental Disclosure Response added no new descriptions of documents or categories of documents.⁴²

Because (1) Plaintiff's sole expert's report addresses no subject other than causation, (2) her Rule 26 disclosures identify no evidence going to any subject other than causation (and damages), (3) she conducted no discovery concerning the product at issue in her case and the Defendants' conduct in designing, manufacturing and marketing the product, and (4) her causation evidence has no probative force under Texas Law, Plaintiff has no evidence to support various essential elements of her claims, and summary judgment should be granted.

(Continued)

73, 81-89, 92 (App. pp. 5, 23, 33-34, 39-44); Fedoruk Report § 6, pp. 9-12, 15-16, § 7, pp. 17-22 (App. pp. 62-65, 68-75).

⁴² See Plaintiff's Rule 26 Initial Disclosure (App. pp. 144-149) and Supplemental Initial Disclosure (App. pp. 150-155).

D. Standards Governing Summary Judgment

The standards governing summary judgment motions were recently explained in *Lofton v. McNeil Consumer & Specialty Pharms.*, 682 F.Supp.2d 662, 670-671 (N.D. Tex. 2010) (parallel citations omitted):

Summary judgment shall be rendered when the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-25 (1986); *Ragas v. Tennessee Gas Pipeline Co.*, 136 F.3d 455, 458 (5th Cir.1998). A dispute regarding a material fact is “genuine” if the evidence is such that a reasonable jury could return a verdict in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

...

Once the moving party has made an initial showing that there is no evidence to support the nonmoving party's case, the party opposing the motion must come forward with competent summary judgment evidence of the existence of a genuine fact issue. *Matsushita Elec. Indus. Co. v. Zenith Radio*, 475 U.S. 574, 586 (1986). Mere conclusory allegations are not competent summary judgment evidence, and thus are insufficient to defeat a motion for summary judgment. *Eason v. Thaler*, 73 F.3d 1322, 1325 (5th Cir.1996). Unsubstantiated assertions, improbable inferences, and unsupported speculation are not competent summary judgment evidence. *See Forsyth v. Barr*, 19 F.3d 1527, 1533 (5th Cir.), *cert. denied*, 513 U.S. 871 (1994). The party opposing summary judgment is required to identify specific evidence in the record and to articulate the precise manner in which that evidence supports his claim. *Ragas*, 136 F.3d at 458. Rule 56 does not impose a duty on the court to “sift through the record in search of evidence” to support the nonmovant's opposition to the motion for summary judgment. *Id.*; *see also Skotak v. Tenneco Resins, Inc.*, 953 F.2d 909, 915-16 & n. 7 (5th Cir.), *cert. denied*, 506 U.S. 832 (1992). “Only disputes over facts that might affect the outcome of the suit under the governing laws will properly preclude the entry of summary judgment.” *Anderson*, 477 U.S. at 248. Disputed fact issues which are “irrelevant and unnecessary” will not be considered by a court in ruling on a summary judgment motion. *Id.* If the nonmoving party fails to make a showing sufficient to establish the existence of an element essential to its case and on which it will bear the burden of proof at trial, summary judgment must be granted. *Celotex*, 477 U.S. at 322-23.

E. Argument and Authority

1. Raub Cannot Establish Medical Causation Under Texas Law

Under Texas law, Raub must establish that her smell loss was caused by exposure to ZCROM.⁴³

In *Merrell Dow Pharmaceuticals, Inc. v. Havner*,⁴⁴ the Texas Supreme Court held that the same factors that are considered in assessing the reliability of the testimony for purposes of admissibility under Texas law also govern a substantive “no evidence” review of scientific evidence.⁴⁵ Texas law recognizes that a toxic tort case such as this, the plaintiff must prove both general and specific causation.⁴⁶ Dr. Pike’s report is insufficient and therefore no evidence of either general or specific causation. In addition to the numerous methodological and foundational shortcomings detected in the accompanying Motion to Exclude, several specific *Havner* requirements are unsatisfied:

- Dr. Pike’s “epidemiological evidence,” a proportional report ratio (PRR) analysis, fails to meet scientific standards – it simply compares the anecdotal reports of smell loss from ZCROM to all other products, not to a control group, or even to a background rate of smell loss in the general population. The analysis is infected with selection bias (inappropriate comparators), informative bias (publicity), and

⁴³ *Cano v. Everest Minerals Corp.*, 362 F.Supp.2d 814, 819 (W. D. Tex. 2005).

⁴⁴ 953 S.W.2d 706 (Tex. 1997). *Havner* also imposed certain standards of requisite epidemiological proof of causation, which are not met by Dr. Pike’s report, and provide an additional ground for summary judgment. See Kip Report ¶¶ 53-54, 72-81 (App. pp. 23-26, 33-39); Fedoruk Report § 6, pp. 12-14 (App. pp. 65-67); see also *Merck Co. v. Garza*, 347 S.W.3d 256 (Tex. 2011)

⁴⁵ 953 S.W.2d at 712-714; see also *Cano*, 362 F.Supp.2d at 821 (admissibility of expert testimony and the legal sufficiency of that evidence are conflated under Texas law in the context of expert testimony).

⁴⁶ *Garza*, 347 S.W.2d 256, 263.

confounding factors (the common cold), and based on unreliable foundational data (AERs data).⁴⁷

- Dr. Pike resorts to reanalysis of AERs data, but ignores the wealth of clinical trial evidence that zinc-based oral cold remedies produced no evidence of smell loss.⁴⁸
- Dr. Pike's theory, and his PRR analysis, has not been published, studied or replicated by the relevant scientific community; they have never been offered outside the courtroom – this courtroom.⁴⁹
- The PRR is a single study, never replicated or verified.⁵⁰
- Dr. Pike's virtually entire general causation analysis is predicated on improper extrapolations from intranasal application evidence.⁵¹
- There is no reliable scientific evidence of target organ exposure.⁵²
- Dr. Pike's report contains no analysis beyond general causation – he simply leaps to the conclusion that ZCROM use was the specific cause of Raub's smell and taste loss, without any consideration of potential alternative causes.⁵³

⁴⁷ Pike Report pp. 29-31 (App. pp. 104-106); *see also* Kip Report ¶¶ 16(vii, viii), 31, 33, 34, 37, 71-80 (App. pp. 5, 10-12, 32-38); Fedoruk Report § 6, pp. 8, 16-17, § 7, p. 20 (App. pp. 61, 69-70, 73); *see also* *Havner*, 953 S.W.2d at 717 (epidemiological study must be properly designed and executed and demonstrate a statistically significant doubling of the risks for those exposed to the substance); *id.* at 718, 724 (epidemiology, commonly shown on assertion, not causation); *id.* at 719 (study and reliable if undermined by confounding factors, selection bias, or information bias).

⁴⁸ *See* Fedoruk Report § 2, p. 2, § 6, p. 12-14 (App. pp. 55, 65-67); *see also* *Havner*, 953 S.W.2d at 720 (expert cannot cherry-pick data to rely on, or reanalyze data to elevate the risk, and still comport with sound scientific methodology).

⁴⁹ *See* *Havner*, 953 S.W.2d at 726-727 (locked publication and peer review and fact that “study was developed specifically for litigation should match court” especially skeptical “if its validity and reliability).

⁵⁰ *See* *Havner*, 953 S.W.2d at 726-727 (located publication and peer review and fact that “study” was developed specifically for litigation should make court “especially skeptical” of its validity and reliability).

⁵¹ *See* Kip Report ¶¶ 16(vi), 63-65, 72 (App. pp. 5, 29-31, 33); Fedoruk Report § 7, p. 20 (App. p. 73).

⁵² *See* Kip Report ¶¶ 16(ix), 63, 86 (App. pp. 5, 29-30, 41); Fedoruk Report § 2, p. 2, 36, pp. 9-12, § 7, pp. 20-21 (App. pp. 55, 62-65, 73-74); *see also* *Havner*, 93 S.W.2d at 720 (requiring evidence of exposure); *Garza*, 347 S.W.3d at 267-268 (emphasizing importance of evidence that plaintiff identify studies showing that the level of their exposure significantly increases the risk).

In short, Dr. Pike has neither reliably ruled in ZCROM as a potential cause (general causation) nor reliably (or at all) ruled out other potential causes (specific causation).

Pursuant to *Havner*, for these reasons and the reasons described in more detail in the companion motion to exclude the testimony of Dr. Pike, there is no evidence that ZCROM caused Raub to lose her sense of smell and taste to support a judgment in favor of Plaintiff, and summary judgment is therefore required.

2. Raub Cannot Recover On Her Claim For Design Defect

To recover for a design defect, Plaintiff must prove that (1) the product was defectively designed so as to render it unreasonably dangerous, (2) a safer alternative design existed, and (3) the defect was a producing cause of the claimed injury.⁵⁴ Plaintiff has no evidence at all to satisfy the first two elements, and the third element fails because her expert's testimony on causation is inadmissible.

Raub has adduced no expert testimony that ZCROM is defectively designed, unreasonably dangerous, or can be feasibly redesigned to make it safer. The only expert testimony she has proffered is Dr. Pike's opinion that her smell and taste loss was caused by ZCROM. Causation is a separate element from defect, unreasonable danger, and the existence of a safer alternative design. Just because a product purportedly causes an injury does not make it defective, unreasonably dangerous, or capable of being designed to be safer.⁵⁵ If it were, then

(Continued)

⁵³ See Pike Report p. 32 (App. p. 107); see also Kip Report ¶¶ 40-46, 94-95 (App. pp. 13-18, 45-46); Fedoruk Report 32, p. 2, § 6, pp. 16-17, § 7, pp. 21-22 (App. pp. 55, 69-70, 74-75); *Havner*, 953 S.W.2d at 720 ("if there are other plausible causes of the injury or condition that could be negated, the plaintiff must offer evidence excluding those causes with reasonable certainty"); *id.* at 711-712 (expert's base opinion or use of "magic words" does not suffice to create evidence of condition).

⁵⁴ *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009).

⁵⁵ *Bic Pen Corp. v. Carter*, 346 S.W.3d 533, 542 (Tex. 2011) (emphasizing that defect, unreasonable danger, and causation are separate and independent requirements).

there would be a single element to satisfy the plaintiff's burden of proof – causation. For this reason, Texas courts have repeatedly held that the mere occurrence of a malfunction, an accident, or an injury is not evidence of a defect, and that expert testimony on the challenged design is necessary to prevail.⁵⁶ In particular, a plaintiff cannot recover without proof that there is a reasonable safer alternative design.⁵⁷

Texas law requires expert testimony to support a challenge to a product's design. Pike's testimony that ZCROM caused Raub's loss of smell and taste, even if it were admissible, is not capable of supporting the additional necessary elements of Raub's design defect claim. Summary judgment should be granted.

3. Raub Cannot Recover On Her Claim For Manufacturing Defect

To recover for a manufacturing defect, plaintiff must prove that the product she used deviates, in construction or quality, from the product's plan or specification, in a manner that renders it unreasonably dangerous and this defect was a producing cause of her injury.⁵⁸ Plaintiff has identified no evidence at all of ZCROM's specifications, or any inspection or analysis of the product she used. There is no report showing deviations from the specifications to her finished product, or that a deviation made the product unreasonably dangerous. Expert testimony is also required to tie the deviation from specifications to the alleged injury.⁵⁹ Dr. Pike's report addresses none of these issues.

⁵⁶ See *Nissan Motor Co., Ltd. v. Armstrong*, 145 S.W.3d 131, 136-138 (Tex. 2004) and cases cited and discussed.

⁵⁷ *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 384 (Tex. 1995); *Dyer v. Danek Medical, Inc.*, 115 F.Supp.2d 732, 738 (N.D. Tex. 2000).

⁵⁸ See *Bic Pen Corp.*, 346 S.W.3d at 540; *Am. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 434 (Tex. 1997).

⁵⁹ *Bic Pen Corp.*, 346 S.W.3d at 542.

4. Raub Cannot Recover On Her Marketing Defect Claims

To recover for a marketing defect (failure to warn), Plaintiff must prove that (1) a risk of harm from the intended or reasonably anticipated use of the product; (2) the defendant supplier knew or reasonably should have foreseen the risk of harm at the time the product was sold; (3) the product contained no warning of this risk; (4) the absence of warning renders the product unreasonably dangerous to the ultimate user or consumer of the product; and (5) the failure to warn caused the user's injury.⁶⁰ Plaintiff has no evidence to satisfy these elements.

Dr. Pike's report addresses none of these issues, other than medical causation. "Texas case law demonstrates a consensus that expert testimony is required in the context of strict liability marketing defect claims"⁶¹ Plaintiff has identified no other evidence which could carry her burden. Accordingly, summary judgment on Plaintiff's marketing defect claim is required.

5. Raub Cannot Recover On Her Breach Of Warranty Claims

Though Plaintiff asserts a breach of express warranty claim, she identifies no express warranty and appears to rely solely on a warranty of fitness for ordinary purposes arising from the sale of the product.⁶² To recover, Plaintiff must prove that (1) the product was defective because it was unfit for its purpose, (2) the defect existed when the product was sold, and (3) the defect caused the injury.⁶³ For the same reasons the defect claims, so does the claim for breach of warranty.⁶⁴

⁶⁰ See *Sims v. Washex Mach. Corp.*, 932 S.W.2d 559, 561 (Tex. App. 1995).

⁶¹ *Ethicon Endo-Surgery, Inc. v. Gillies*, 343 S.W.3d 205, 212 (Tex. App. 2011).

⁶² See Plaintiff's Complaint ¶¶ 17-18 (App. p. 139).

⁶³ See *Scott v. Dorel Juvenile Group, Inc.*, 773 F.Supp.2d 664, 673 (N.D.Tex. 2011); *Sipes v. General Motors Corp.*, 946 S.W.2d 143, 158 (Tex. App. 1997); *Nobles v. Sofamor, S.N.C.*, 81 F.Supp.2d 735, 741 (S.D. Tex. 1999).

⁶⁴ See *Hyundai Motor Co. v. Rodriguez*, 995 S.W.2d 661 (1999).

6. Raub Cannot Recover On Her Negligence Claims

To prevail on her negligence claims, Plaintiff must prove that her injury was caused by a defect in the product and the defect resulted from a failure by the defendant to exercise ordinary care in the design, manufacture or marketing of the product.⁶⁵ Plaintiffs' claims for negligence fail for the same reasons as her defect claims, and for the additional reason that she has identified no evidence that Defendants failed to exercise reasonable care in the design, manufacture and marketing of ZCROM. Nor could she, given her failure to take any depositions concerning the design, manufacture, and marketing of the product.

7. Raub Is Barred From Recovering Damages For Bodily Injury Under The DTPA

Raub's Complaint purports to assert a claim for violations of the DTPA.⁶⁶ Defendants are entitled to summary judgment because Raub's claim is for bodily injury, and such claims, with limited exceptions not applicable here, are not allowed under the DTPA.⁶⁷

In 1995, the Texas Legislature revised the DTPA to exempt causes of action for bodily injury or death and, because the statute's language is clear and unambiguous, the Court should adopt the interpretation that the statute's words plainly support.⁶⁸

Except as specifically provided by subsections (b) and (h), Section 17.50, nothing in this subchapter shall apply to a cause of action for bodily injury or death or for the infliction of mental anguish.⁶⁹

Prior to the 1995 amendment, the DTPA had been expanded beyond its intended scope, including personal injury litigation.⁷⁰ Thus, one of the aims of the Legislature in reforming the

⁶⁵ See *Ethicon Endo-Surgery, Inc. v. Gillies*, 343 S.W.3d at 212; *Am. Tobacco Co. v. Grinnell*, 951 S.W.2d at 437.

⁶⁶ See Plaintiff's Complaint at ¶ 16 (App. p. 139).

⁶⁷ See *DiGangi v. 24 Hour Fitness USA, Inc.*, 2005 WL 1367945, *2-3 (Tex. App. June 10, 2005).

⁶⁸ See *Fitzgerald v. Advanced Spine Fixation Sys., Inc.*, 996 S.W.2d 864, 865-66 (Tex. 1999).

⁶⁹ TEX. BUS. & COMM. CODE ANN. §17.49(e) (Vernon 2005).

⁷⁰ See Teel Bivins et al., *The 1995 Revisions to the DTPA: Altering the Landscape*, 27 TEX. TECH. L. REV. 1441, 1448 (1996).

DTPA was to exclude personal injury litigation from its ambit.⁷¹ Public policy supports this limitation because personal injury litigants may still seek relief through traditional forms of action such as negligence, strict products liability, and breach of warranty – as Raub has done here – to the extent such a claim is supported.

Raub's claim is for bodily injury. She claims her use of ZCROM caused loss of her senses of smell and taste.⁷² All of her claims derive from these bodily injuries, including loss of pleasure and mental pain and suffering.⁷³ These are not economic damages recoverable under the DTPA.

Moreover, Raub has produced no evidence supporting recovery under the two limited exceptions which allow a cause of action for bodily injury or mental anguish to proceed. Section 17.49(e) makes clear that a cause of action for bodily injury or mental anguish may *only* be brought under the DTPA *if* allowed under Section 17.50(b) or (h).⁷⁴

Section 17.50(b) allows a consumer to recover mental anguish damages, in addition to economic damages, if a DTPA violation was committed knowingly or intentionally; but it does not abrogate the Legislature's amendment, which was intended to remove most personal injury claims from the ambit of the DTPA. Regardless, even if Raub were allowed to assert a claim for economic damages under 17.50(b), she has already admitted that she has not suffered economic damages.⁷⁵ Thus, section 17.50(b) does not provide Raub a means for recovery under the DTPA.

Section 17.50(h) only permits a DTPA claimant to recover *actual* damages, which can include bodily injury or death claims and not just economic damages, *if* she is granted the right to

⁷¹ *Id.* at 1443.

⁷² See Plaintiff's Complaint at ¶¶ 13-15, 21, 24, and pp. 9-10 (App. p. 138-139, 140-143).

⁷³ See Raub Dep. pp. 90:2-92:15 (App. pp. 224-226).

⁷⁴ See TEX. CIV. PRAC. & REM. CODE ANN. § 17.49(e) (Vernon 2005).

⁷⁵ See Raub Dep. pp. 90:2-92:15 (App. pp. 224-226).

bring a cause of action under the DTPA by another law, such as the Business Opportunity Act or the Debt Collection Act, etc.⁷⁶ This is commonly referred to as the “tie-in statutes” provision. Raub has not produced evidence that she is entitled to recover damages based on a tie-in statute, nor has she even alleged a right to recovery under the DTPA by application of a tie-in statute. Thus, section 17.50(h) does not permit her to recover damages for bodily injury.

Because Raub’s bodily injury claim is the very kind specifically excluded from the DTPA, and because Raub has produced no evidence establishing that the DTPA bodily injury exceptions apply, Defendants are entitled to summary judgment.

8. Raub Has No Evidence To Support Her Claims Of Gross Negligence, Malice, Or Fraud

Despite her opportunity to conduct discovery, Raub has not identified any evidence to support her claims of gross negligence, fraud, or malice. Thus, Defendants are entitled to summary judgment on each of these claims.

a. Gross Negligence And Malice

To support a finding of either gross negligence or malice, Raub must show that (1) viewed objectively from Defendants’ standpoint, the act or omission complained of involved an extreme degree of risk, considering the probability and magnitude of the potential harm to her;⁷⁷ and (2) Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded in conscious indifference to her safety.⁷⁸ She cannot meet these standards.

Extreme risk is a function of both the magnitude and the probability of the anticipated injury to the plaintiff. . . . [T]he “extreme risk” prong is not satisfied

⁷⁶ TEX. BUS. & COMM. CODE ANN. § 17.50(h) (Vernon 2005).

⁷⁷ *Transportation Ins. Co. v. Moriel*, 879 S.W.2d 10, 23 (Tex. 1994). The objective prong of a gross negligence cause of action imposes a threshold showing significantly higher than the objective “reasonable person test for negligence.” *Id.* at 21-22.

⁷⁸ *See Louisiana-Pac. Corp. v. Andrade*, 19 S.W.3d 245, 246 (Tex. 1999); *see also* TEX. CIV. PRAC. & REM. CODE ANN. § 41.001(7)(A) (West 1999).

by a remote possibility of injury or even a high probability of minor harm, but rather “the likelihood of serious injury” to the plaintiff. [Citations and emphasis omitted.] An act or omission that is merely thoughtless, careless or not inordinately risky cannot be grossly negligent. Only if the defendant’s act or omission is unjustifiable and likely to cause serious harm can it be grossly negligent.^{79]}

There is no evidence of an act or omission by Defendants that involved an extreme degree of risk, or that Defendants acted with specific intent to cause any bodily injury to Raub. Moreover, there is no evidence that Defendants had any actual, subjective awareness of any risk to Raub, or that they acted with conscious indifference to her safety. Because there is no evidence to support Raub’s claims of gross negligence and malice, Defendants are entitled to summary judgment as a matter of law on these claims.

b. Fraud

In Texas, the common law elements of actionable fraud are that: (1) Defendants made a material misrepresentation; (2) the representation was false; (3) when the representation was made, Defendants knew it was false or made it recklessly and as a positive assertion without any knowledge of its truth; (4) Defendants made the representation intending the plaintiff to rely on it; (5) the plaintiff in fact relied on the representation; and (6) thereby suffered injury.⁸⁰

While Raub’s pleadings allege that Defendants misrepresented the safety of ZCROM, there is no evidence establishing Defendants’ intent, Raub’s reliance, or that her reliance, if any, caused her injury. In fact, Raub testified that she purchased the product because she thought it might help with her cold; she did not claim her purchase was based on any representation about its safety.⁸¹ She therefore did not rely on any representations made by

⁷⁹ *Moriel*, 879 S.W.2d at 22.

⁸⁰ *See Eagle Props., Ltd. v. Scharbauer*, 807 S.W.2d 714, 722-23 (Tex. 1990).

⁸¹ *See* Raub Dep. pp. 58:4-14, 60:14-17 (App. pp. 204, 206).

Defendants about the safety of the product – an essential element of her fraud claim.⁸² Since Raub cannot produce any evidence establishing the essential elements for her fraud claim, Defendants are also entitled to summary judgment on this cause of action.

9. Raub Has No Evidence To Support Her Demand For Punitive Damages

Texas Civil Practice & Remedies Code section 41.003 requires that Raub to prove by clear and convincing evidence that Defendants were grossly negligent, malicious, or that they committed fraud.⁸³ Nothing in Plaintiffs' Rule 26 disclosures identifies any support for a claim that Defendants engaged in this type of behavior regarding the marketing of ZCROM, and no discovery conducted by Plaintiff unearthed any such evidence – again, Plaintiff took no depositions of Defendants or their employees in this case. Thus, Raub has no evidence establishing any of the criteria for a punitive damages award, and she is not entitled to recover punitive damages from Defendants.

⁸² Raub's Rule 26 disclosures did not identify any evidence establishing her reliance on any representations, or even any evidence that the ad she saw before she purchased the product related to ZCROM, as opposed to some other Zicam product.

⁸³ TEX. CIV. PRAC. & REM. CODE ANN. § 41.003 (Vernon 2005). Importantly, Raub cannot satisfy her burden of proof by evidence of Defendants' ordinary negligence, bad faith or deceptive trade practice.

CONCLUSION

WHEREFORE PREMISES CONSIDERED, Defendants Matrixx Initiatives, Inc. and Zicam L.L.C. respectfully request that this Court grant this No-Evidence Motion for Summary Judgment in its entirety, or in the alternative, for Partial Summary Judgment, and that the Court also grant these parties such other relief to which they may be justly entitled.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the above and foregoing Motion for Summary Judgment has been forwarded to all counsel of record via the Court's electronic filing system and/or by placing same in the U.S. Mail, postage prepaid and properly addressed on this 4th day of June, 2012.

By: /s/ Kealy C. Sehic
Kealy C. Sehic